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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,140	09/16/2003	Christine Henry	8707-2163	3993
7590 05/10/2006				
Robert M. Isackson Orrick, Herrington & Sutcliffe, LLP 666 Fifth Avenue New York, NY 10103			EXAMINER KRAMER, NICOLE R	
			ART UNIT 3762	PAPER NUMBER
DATE MAILED: 05/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,140

Applicant(s)

HENRY ET AL.

Examiner

Nicole R. Kramer

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,074,308 ("Sholder et al") in view of U.S. Patent No. 5,462,060 ("Jacobson et al.").

Sholder et al. discloses a pacemaker (10) including means for sensing ventricular and atrial cardiac activity (leads 16 and 22 and corresponding sensing amplifiers 18 and 20), means for delivering an antitachycardia therapy able to apply selectively a defibrillation shock, a cardioversion shock and an antitachycardia pacing stimulation (pulse generator and control logic 12), means for detecting patient activity and means for delivering antibradycardia stimulation according to detected patient activity (Sholder et al. discloses that pacemaker 10 may be a rate-responsive pacemaker; see col. 8, lines 20-22. When pacemaker 10 is a rate-responsive pacemaker, it necessarily includes means for detecting patient activity). Sholder discloses means for analyzing the detected cardiac activity with respect to a given threshold frequency of analysis and determining a frequency of cardiac activity (pacemaker 10 determines whether the heart

rate exceeds a tachycardia reference rate; see col. 16, lines 23-54). Sholder discloses that the tachycardia reference rate may be less than the maximum tracking rate of the pacemaker, which Examiner considers to be the maximum frequency stimulation of claim 1 (see, for example, col. 13, line 38 - col. 14, line 3). In response to a detected tachycardia, pacemaker 10 changes the P-V delay and evaluates the resulting cardiac cycle in order to distinguish a natural fast heart rate condition from a pacemaker mediated tachycardia (see, col. 14, lines 39-58 and col. 15, lines 20-40).

Sholder et al. fails to disclose that the pacemaker includes means for discriminating between a ventricular tachycardia and a ventricular fibrillation. Jacobson et al. teaches a pacemaker algorithm for discriminating between a ventricular tachycardia and a ventricular fibrillation (see Fig. 1). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker disclosed in Sholder et al. to discriminate between a ventricular tachycardia and a ventricular fibrillation as taught by Jacobsen et al. in order to enable the pacemaker to deliver the most appropriate therapy for a detected, abnormal heart rate.

With respect to claims 2 and 4-5, the pacemaker of Sholder et al. is capable of detecting an occurrence of a ventricular extrasystole via leads 16 and 22 because the pacemaker is continuously detecting cardiac activity.

With respect to claim 3, Jacobsen et al. teaches means for identifying the origin of the cardiac event (see Fig. 1).

With respect to claim 6, Sholder et al. discloses that the pacemaker includes means for detecting a presence of a confirmed rate of ventricular tachycardia

(pacemaker 10 determines whether the heart rate exceeds a tachycardia reference rate; see col. 16, lines 23-54).

With respect to claims 7-9, Sholder et al. discloses that in response to a detected tachycardia, pacemaker 10 changes the P-V delay and evaluates the resulting cardiac cycle in order to distinguish a natural fast heart rate condition from a pacemaker mediated tachycardia (see, col. 14, lines 39-58 and col. 15, lines 20-40). The pacemaker is inherently capable of changing the P-V delay to a tachycardia detection time interval increased by a predetermined, programmable safety factor.

Response to Arguments

3. Applicant's arguments filed 4/18/06 have been fully considered but they are not persuasive. More specifically, Applicant argues that neither Sholder nor Jacobsen disclose a first analyzing means able to recognize and discriminate the presence of a ventricular tachycardia and a ventricular fibrillation. In the Office Action dated 12/27/05, Examiner acknowledged that Sholder et al. fails to disclose that the pacemaker includes means for discriminating between a ventricular tachycardia and a ventricular fibrillation (see page 4 of Office Action dated 12/27/05). However, Examiner relied on Jacobson et al. to teach this claimed feature, stating that Jacobson et al. teaches a pacemaker algorithm for discriminating between a ventricular tachycardia and a ventricular fibrillation (see Fig. 1). Fig. 1 of Jacobson et al. teaches the methodology for discriminating between ventricular fibrillation (see steps 11, 12, 21 which declare and treat VF), ventricular tachycardia VT (see steps 20, 16, and 22 which declare and treat

VT), sinus tachycardia (see steps 18 and 19 which declare ST), and super-ventricular tachycardia (see steps 14 and 23 which declare and treat SVT). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker disclosed in Sholder et al. to discriminate between a ventricular tachycardia and a ventricular fibrillation as taught by Jacobsen et al. in order to enable the pacemaker to deliver the most appropriate therapy for a detected, abnormal heart rate.

4. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

5. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Examiner maintains that it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker disclosed in Sholder et al. to discriminate between a ventricular tachycardia and a ventricular fibrillation as taught by Jacobson et al. *in order to enable the pacemaker to deliver the most appropriate therapy for a detected, abnormal heart rate.* This motivation is found in the Jacobson et al. reference (see col. 9, lines 5-10 which teaches that the device delivers the appropriate therapy for the declared cardiac condition), and is also in the knowledge generally available to one of ordinary skill in the art (that is, that it is desirable for the pacemaker to identify an abnormal cardiac rhythm as particularly as possible in order to effectively treat the cardiac condition).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NRK
4/24/06


George Manuel
Primary Examiner